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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
10/080,980	02/21/2002	John N. Feder	D0121.NP	9974

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EXAMINER
PAPPU, SITA S

ART UNIT	PAPER NUMBER
1636	5

DATE MAILED: 07/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/080,980	FEDER ET AL.	
	Examiner	Art Unit	
	Sita Pappu	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-19* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
4) ☐ Interview Summary (PTO-413) Paper No(s) _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other

DETAILED ACTION

Claims 1-19 are pending in the instant application.

Sequence Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

Sequences are disclosed in the specification but are not identified by their sequence identifiers (i.e. SEQ ID NO). For example, the specification on page 216 discloses amino acid sequences, that are not identified by sequence identifiers. Applicant is further reminded that amendment to the specification, and/or figures is required to comply with 37 C.F.R. 1.821(d). Each sequence disclosed in the specification and figures must be identified by its sequence identifier (i.e., SEQ ID NO:). Since the specification discloses sequences that are not identified by their sequence identifier, it is unclear if all disclosed sequences are included in the sequence listing. Applicant is advised that, a substitute CRF and paper copy of the Sequence Listing are required only if the sequences are not already included in the Sequence Listing.

Applicant is reminded that the entire specification and figures should be reviewed for sequence disclosures.

Applicant is given ONE MONTH from the mailing date of this communication within which to comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, 8, 9, 12, 14-17, drawn to an isolated nucleic acid molecule comprising SEQ ID NO:1 in its variant forms, vector, host cell, a method of making, and a method of diagnosing a pathological condition by determining the presence or absence of a mutation in the polynucleotide, classified in class 435, subclass 320.1.

II. Claims 5, 6, 10, 13, 18, drawn to an isolated polypeptide, and a method of diagnosing a pathological condition by determining the presence or amount of ecpression the polypeptide in a biological sample, classified in class 530, subclass 300+.

III. Claim 7, drawn to an antibody, classified in class 530, subclass 387.1+.

IV. Claims 11, 19, drawn to a method for preventing, treating or ameliorating a medical condition by administering a polypeptide, classified in class 514, subclass 2+.

V. Claims 11, 19, drawn to a method for preventing, treating or ameliorating a medical condition by administering a polynucleotide, classified in class 514, subclass 44.

Claims 11, 19 embrace the Inventions of Groups IV and V. Should either of the Inventions IV or V be elected, the claims 11, 19 will be examined only to the extent they encompass the subject matter elected.

The inventions are distinct, each from the other because of the following reasons:

Invention I is directed to a nucleic acid molecule while Invention II is directed to a polypeptide. Polypeptides and nucleic acids are substantially different in terms of structural, chemical, physical and biological properties, are made using substantially different techniques and can be used for substantially different purposes. It is particularly noted that the nucleic acid is not required for the production of the peptide as peptides can be synthesized or purified from cells.

Invention III is directed to an antibody which structurally different from the polynucleotide of Group I and the polypewptide of Group II and exhibits different properties and modes of action and produces different effects.

Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially

different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotide can be used in the process of Invention I and also Invention IV which are materially different.

Inventions II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotide can be used in the process of Invention II and also Invention V which are materially different.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper. Further, the search required for one Group is not required for other Groups.

Claims 11 and 19 are directed to treating a plurality of disclosed patentably distinct diseases comprising a gastrointestinal disorder, a reproductive disorder, an immune disorder, a neural disorder, a cardiovascular disorder, a pulmonary disorder, a disorder related to hyper potassium channel activity, an immune disorder related to aberrant NF-kB activity, pineal gland associated disorders, migraine headaches,

disorders associated with aberrant melatonin synthesis and/or release, delayed sleep phase syndrome, aberrations in circadian cycle, mammary cancer tumorigenesis, disorders associated with low DNA repair capacities or low free-radical buffering capacity, sleep disorders, age related disorders associated with decreased melatonin secretion, and cancer. These diseases and/or syndromes are associated with different pathologies and etiologies. Further, animals that are models of these diseases will exhibit phenotypes that are distinct from one another. Applicant is required under 35 U.S.C. 121 to elect a single disclosed disease for examination, even though this requirement is traversed.

Should applicant traverse on the ground that the diseases are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the diseases to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sita S Pappu whose telephone number is (703) 305-5039. The examiner can normally be reached on Mon-Fri (8:30 AM - 5:00 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached on (703) 305 1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308 4242 for regular communications and (703) 872 9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, Tracey Johnson, whose telephone number is (703) 305-2982.

Anne-Marie Baker

ANNE-MARIE BAKER
PATENT EXAMINER

S. Pappu
July 18, 2002